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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,791	04/25/2001	David Russell Blake	9374.21USWO	3690

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/08/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	09/763,791	BLAKE ET AL.
	Examiner	Art Unit
	Jon P. Weber, Ph.D.	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) 19-31, 36 and 37 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 and 33-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

Status of the Claims

The response with amendments filed 22 July 2002 has been received and entered. Claims 1-31 and 33-37 have been presented for examination.

Election/Restrictions

This application contains claims 19-31, 36 and 37 drawn to an invention nonelected **with** traverse in Paper No. 9, filed 04 December 2001. A complete reply to the final rejection **must** include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claim 11 is now rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 now recites “the second portion being sterilized” which says what you do to the portion but does not clearly indicate what the portion is.

Claim Rejections - 35 USC § 102

It is argued that the claims now require a formula feed that is nutritionally complete. It is urged that a formula feed is generally understood in the art to be specifically designed to feed infants and to exclude milk products *per se*.

The argument is not supported by evidence that formula feed is limited to infant formulas. The term is broader than infant formula and includes any formulation that can be used as a feed, and as claimed, for any organism. Further the argument that formula feed excludes milk products is contrary to the disclosure at page 3, line 28 to page 4, line 1, wherein it is clearly stated that formula feeds according to the instant invention based on cow's milk or soy are encompassed.

The term "nutritionally complete" only has meaning with respect to the organism being fed. Many microbes only need a carbon source and nitrogen source to grow. In terms of humans, "nutritionally complete" implies that the full complement of amino acids as well as carbohydrate, fats, minerals and vitamins are provided. It is well known in the art that milk is a complete food. Cow's milk does not provide the same balance of nutrients as human milk. Hence, cow's milk based formulas are generally modified for human consumption. However, the instant claims are not limited to human consumption. Cow's milk is quite complete for cattle.

Claims 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Björck et al. (1979).

There is no reason why the solution disclosed by Björck et al. (1979) could not be used as the formulation of these claims. The functional intended use of the solution does not materially change the solution.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claims 1, 7-8, 11, 15 and 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cooray et al. (1995).

Cooray et al. (1995) specifically disclose a formulation wherein xanthine oxidase is added to cow's milk. The addition of exogenous xanthine oxidase to the milk makes it a formulation within the broadest reasonable interpretation of the word and giving it its ordinary meaning. Since, they are mixed together, one can consider the two samples just before mixing to be a kit.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claims 1-4, 6-11, 14-17 and 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (1976).

The basis for the assertion that the formulation of Clark et al. (1976) is incomplete is unfounded.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claims 1-17 and 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ho et al. (1978).

The basis for the assertion that the formulation of Ho et al. (1978) is incomplete is unfounded.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claims 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Zikakis (US 4,238,566).

There is no reason why the solution disclosed by Zikakis (US 4,238,566) could not be used as the formulation of these claims. The functional intended use of the solution does not materially change the solution.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claims 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Antrim et al. (US 4,961,939).

There is no reason why the solution disclosed by Antrim et al. (US 4,961,939) could not be used as the formulation of these claims. The functional intended use of the solution does not materially change the solution.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claims 1, 6-10 and 33-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by De Jong et al. (US 5,747,078).

The basis for the assertion that the formulation of De Jong et al. (US 5,747,078) is incomplete is unfounded.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 103

Claims 1-18 and 33-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Björck et al. (1979), Ho et al. (1978), Clark et al. (1976), Zikakis (US 4,238,566), Antrim et al. (US 4,961,939) and De Jong et al. (US 5,747,078) in view of Reddy et al. (US 5,876,990).

It is argued that primary references do not disclose all of the elements, i.e., a nutritionally complete formula feed, and the secondary reference does not remedy this deficiency. Hence, a *prima facie* case of obviousness has not been made.

As discussed above, the primary references do disclose nutritionally complete formula feed. Reddy et al. (US 5,876,990) was not cited to remedy this alleged deficiency, but to

establish that one could treat Scours with the composition. A *prima facie* case of obviousness has been made.

Applicant's arguments filed 22 July 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 103(a) is adhered to for the reasons of record and the additional reasons above.

Other references cited by examiner but not relied upon are:

1. Stott et al. (US 4,834,974) disclose adding an immunologically active filtrate that contains xanthine oxidase to feeds for neonates.
2. Burr, II (US 4,389,425) discloses a nutritionally complete soy based milk infant formula feed that contains lower amounts of xanthine oxidase compared to bovine milk.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

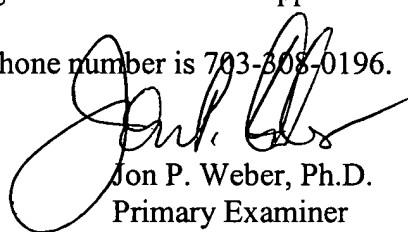
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
October 2, 2002